

Medication Guide

TYLENOL[®] (TAHY-luh-nawl) with Codeine Tablets, CIII

TYLENOL[®] with Codeine is:

- A strong prescription pain medicine that contains an opioid (narcotic) that is used to manage mild to moderate pain, when other pain treatments such as non-opioid pain medicines do not treat your pain well enough or you cannot tolerate them.
- An opioid pain medicine that can put you at risk for overdose and death. Even if you take your dose correctly as prescribed, you are at risk for opioid addiction, abuse, and misuse that can lead to death.

Important information about TYLENOL[®] with Codeine:

- **Get emergency help right away if you take too much TYLENOL[®] with Codeine (overdose).** When you first start taking TYLENOL[®] with Codeine, when your dose is changed, or if you take too much (overdose), serious or life-threatening breathing problems that can lead to death may occur.
- TYLENOL[®] with Codeine can cause severe drowsiness, breathing problems (respiratory depression), coma and death when taken with benzodiazepines or other medicines that depress consciousness.
- Never give anyone else your TYLENOL[®] with Codeine. They could die from taking it. Store TYLENOL[®] with Codeine away from children and in a safe place to prevent stealing or abuse. Selling or giving away TYLENOL[®] with Codeine is against the law.

Do not take TYLENOL[®] with Codeine if you have:

- severe asthma, trouble breathing, or other lung problems.
- a bowel blockage or narrowing of the stomach or intestines.
- previously had an allergic reaction to codeine or acetaminophen.

Before taking TYLENOL[®] with Codeine, tell your healthcare provider if you have a history of:

- head injury, seizures
- liver, kidney, thyroid problems
- problems urinating
- pancreas or gallbladder problems
- abuse of street or prescription drugs, alcohol addiction, or mental health problems.

Tell your healthcare provider if you are:

- **pregnant or planning to become pregnant.** Prolonged use of TYLENOL[®] with Codeine during pregnancy can cause withdrawal symptoms in your newborn baby that could be life-threatening if not recognized and treated.
- **breastfeeding.** TYLENOL[®] with Codeine passes into breast milk and may harm your baby.
- taking prescription or over-the-counter medicines, vitamins, or herbal supplements. Taking TYLENOL[®] with Codeine with certain other medicines can cause serious side effects that could lead to death.

When taking TYLENOL[®] with Codeine:

- Do not change your dose. Take TYLENOL[®] with Codeine exactly as prescribed by your healthcare provider. Use the lowest dose possible for the shortest time needed.
- Take your prescribed dose every 4 hours as needed. Do not take more than your prescribed dose. If you miss a dose, take your next dose when needed.
- Call your healthcare provider if the dose you are taking does not control your pain.
- If you have been taking TYLENOL[®] with Codeine regularly, do not stop taking TYLENOL[®] with Codeine without talking to your healthcare provider.

This Medication Guide has been approved by the U.S. Food and Drug Administration.

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- After you stop taking TYLENOL® with Codeine dispose of any unused tablets in accordance with local state guidelines and/or regulations.

While taking TYLENOL® with Codeine DO NOT:

- Drive or operate heavy machinery, until you know how TYLENOL® with Codeine affects you. TYLENOL® with Codeine can make you sleepy, dizzy, or lightheaded.
- Drink alcohol or use prescription or over-the-counter medicines that contain alcohol. Using products containing alcohol during treatment with TYLENOL® with Codeine may cause you to overdose and die.

The possible side effects of TYLENOL® with Codeine:

- constipation, nausea, sleepiness, vomiting, tiredness, headache, dizziness, abdominal pain. Call your healthcare provider if you have any of these symptoms and they are severe.

Get emergency medical help if you have:

- trouble breathing, shortness of breath, fast heartbeat, chest pain, swelling of your face, tongue, or throat, extreme drowsiness, light-headedness when changing positions, feeling faint, agitation, high body temperature, trouble walking, stiff muscles, or mental changes such as confusion.

These are not all the possible side effects of TYLENOL® with Codeine. Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088. For more information go to dailymed.nlm.nih.gov.

Manufactured by: Janssen Ortho, LLC, Gurabo, Puerto Rico 00778. Manufactured for: Janssen Pharmaceuticals, Inc., Titusville, NJ 08560. 1-800-526-7736

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